

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 522

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Certifier G. Penley

Implantation or Injectable Dosage Form New Animal Drugs; Gonadorelin
Diacetate Tetrahydrate

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of an abbreviated new animal drug application (ANADA) filed by Phoenix Scientific, Inc. The ANADA provides for use of gonadorelin diacetate tetrahydrate solution by injection in dairy cattle for the treatment of ovarian cysts.

DATES: This rule is effective [*insert date of publication in the Federal Register*].

FOR FURTHER INFORMATION CONTACT: Lonnie W. Luther, Center for Veterinary Medicine (HFV-104), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 301-827-8549, e-mail: lluther@cvm.fda.gov.

SUPPLEMENTARY INFORMATION: Phoenix Scientific, Inc., 3915 South 48th St. Terrace, P.O. Box 6457, St. Joseph, MO 64506-0457, filed ANADA 200-069 that provides for veterinary prescription use of FERTELIN (gonadorelin diacetate tetrahydrate) Injection by intramuscular or intravenous injection in dairy cattle for the treatment of ovarian cysts. Phoenix's FERTELIN Injection is approved as a generic copy of Merial, Ltd.'s CYSTORELIN, approved under NADA 98-379. ANADA 200-069 is approved as of August 26, 2002, and the regulations are amended in § 522.1078 (21 CFR 522.1078) to reflect the

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approval. Section 522.1078 is also being revised to reflect a current format. The basis of approval is discussed in the freedom of information summary.

In accordance with the freedom of information provisions of 21 CFR part 20 and 514.11(e)(2)(ii), a summary of safety and effectiveness data and information submitted to support approval of this application may be seen in the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday.

The agency has determined under 21 CFR 25.33(a)(1) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

This rule does not meet the definition of "rule" in 5 U.S.C. 804(3)(A) because it is a rule of "particular applicability." Therefore, it is not subject to the congressional review requirements in 5 U.S.C. 801-808.

List of Subject in 21 CFR Part 522

Animal drugs.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR part 522 is amended as follows:

PART 522—IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS

1. The authority citation for 21 CFR part 522 continues to read as follows:

Authority: 21 U.S.C. 360b.

2. Section 522.1078 is revised to read as follows:

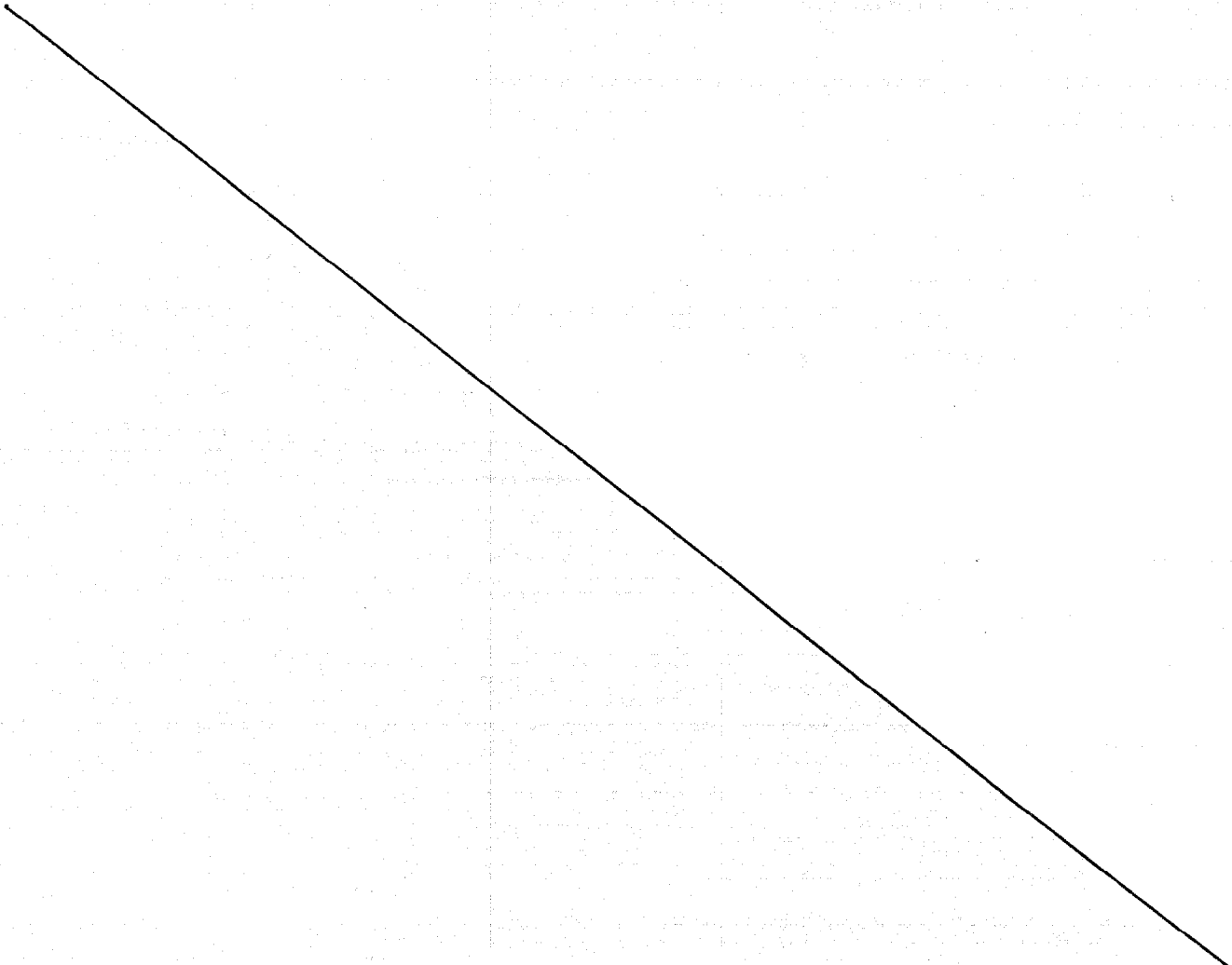
§ 522.1078 Gonadorelin diacetate tetrahydrate.

(a) *Specifications.* Each milliliter of solution contains 50 micrograms (μg) of gonadorelin diacetate tetrahydrate.

(b) *Sponsors.* See Nos. 050604, 057926, and 059130 in § 510.600(c) of this chapter.

(c) *Conditions of use in cattle.* It is used as follows:

(1) *Amount.* 100 μg per cow as a single intramuscular or intravenous injection.



(2) *Indications for use.* For the treatment of ovarian cysts in dairy cattle.

(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

Dated: 10/28/02
October 28, 2002.

S F Sundlof

Stephen F. Sundlof,
Director,
Center for Veterinary Medicine.

[FR Doc. 02-????? Filed ??-??-02; 8:45 am]

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Glenn Presley